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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/608,875	06/27/2003	Harish Makker	27542(51308-00090)	7856

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EXAMINER	
BRUENJES, CHRISTOPHER P	
ART UNIT	PAPER NUMBER
1772	

DATE MAILED: 04/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/608,875	MAKKER ET AL.	
	Examiner	Art Unit	
	Christopher P. Bruenjes	1772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *18-43,46 and 51-56* is/are pending in the application.

4a) Of the above claim(s) *18-31* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *32-43,46 and 51-56* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 7, 2006 has been entered.

WITHDRAWN REJECTIONS

2. The claim objections of claims 46-50 of record in the Office Action mailed November 7, 2005, Pages 2-3 Paragraphs 2-3, have been withdrawn due to Applicant's cancellation of those claims in the Paper filed February 7, 2006.

3. The 35 U.S.C. 112 rejections of claims 44, 45, and 47-50 of record in the Office Action mailed November 7, 2005, Pages 3-4 Paragraph 4, have been withdrawn due to Applicant's amendments in the Paper filed February 7, 2006.

4. The 35 U.S.C. 103 rejections of claims 32-50 over Yang in view of Luthra of record in the Office Action mailed November 7, 2005, Pages 5-8 Paragraph 5, have been withdrawn due to Applicant's arguments in the Paper filed February 7, 2006.

Claim Objections

5. Applicant is advised that should claims 43 and 51-53 be found allowable, claims 46 and 54-56 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 32-33 and 36-42 are rejected under 35 U.S.C. 102(b) as being anticipated by Goldberg et al (USPN 5,290,548).

Goldberg et al anticipate a lubricious coating covalently bonded to the surface of a medical device (see abstract and col.4, l.49-61 and col.6, l.23-48). Note the limitation "an intraocular lens inserter cartridge" is merely a limitation stating the identity and use of the article claimed in the preamble and does not provide any structural limitations with regard to what differentiates an intraocular lens inserter cartridge from other articles, especially tubular articles. Articles are defined by structure, not what the article does. In this case little patentable weight is give to the preamble because it does not provide structural limitations to the article claimed, other than the fact that the article must have a structure that would enable it to insert an intraocular lens. Goldberg et al teach that the hydrophilic coating, which is a lubricious coating, is covalently bound to the surface of intraocular lenses or to lens glides (col.7, l.36-55). A lens glide has the structure capable of inserting an intraocular lens and therefore reads on the preamble limitation "an intraocular lens inserter cartridge". The coating would be applied to at least one IOL-contacting surface of the lens glide in order to improve the tissue contacting characteristic of the surface.

Goldberg et al teach that the hydrophilic coating, which is a lubricious coating, is methoxy polyethylene glycol monomethacrylate (col.17, l.30-35). The monomethacrylate is the reactive substituent component comprising an ethylenically unsaturated group such as methacrylic groups. The polyethylene glycol is the lubricity enhancing component as an alkylene oxide. Specifically, Goldberg et al provides an example of using a high molecular weight mPEGMA (col.17, l.40-42). The second substituent component effective to reduce hydrolysis of said lubricity enhancing component is methoxy, which is an alcoxy group having 1 carbon atom, which is a specific hydrocarbyl group.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for

establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. Claims 43, 46, and 51-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldberg et al (USPN 5,290,548).

Goldberg et al teach all that is claimed in claim 42 as shown above, and teach that the lubricity enhancing component is polyethylene glycol. Goldberg et al fail to teach that mPEGMA comprises mPEGMA of at least three different molecular weights. However, Goldberg et al teach mPEGMA of various PEG molecular weights are used (col.17, l.39-42) and teach that more than one hydrophilic monomer is used together (col.11, l.10-14) and teach that optimum results of the coating are obtained by selection of a combination of process parameters, monomers, and conditions (col.10, l.50-54). One of ordinary skill in the art would have recognized that through routine experimentation one would arrive at the optimum combination of monomers including three different molecular weight mPEGMA such as 1100, 526, and 360, depending on

the intended end result of the coating and article the coating is applied, as taught by Goldberg et al.

Therefore, it would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made to select the mPEGMA as a combination of at least three different molecular weight mPEGMA wherein at least one of said three is has a molecular weight of 1100, or 526, or 360, absent the showing of unexpected result, since Goldberg et al teach that it is known to combine multiple hydrophilic components to form the coating and that mPEGMA is selected form various molecular weight mPEGMA and since the specific selection of monomers in the coating are determined through routine experimentation to optimize the results of the coating on the end product.

11. Claims 32-43, 46, and 51-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yang et al (USPN 5,803,925) in view of Goldberg et al (USPN 5,290,548).

Yang et al teach an intraocular lens inserter cartridge comprising a lubricious coating covalently bound to at least one IOL-contacting surface of said IOL insert cartridge (see abstract). The lubricous coating comprises a reactive substituent component for covalently bonding said lubricious

coating to said IOL-contacting surface and a lubricity enhancing component wherein said lubricity enhancing component further comprises a first substituent component for providing lubricity (col.5, l.19-34).

Yang et al fail to teach that the coating also includes a second substituent component effective to reduce hydrolysis of said lubricity enhancing component. However, Goldberg et al teach that polyethylene glycol coatings such as the coating of Yang et al provide medical devices and particularly lens glides such as the intraocular lens inserter cartridge of Yang et al with a good biocompatible lubricious hydrophilic coating (col.17, l.30-42). Goldberg et al also teach that a preferred polyethylene glycol coating for medical devices is a methoxy polyethylene glycol monomethacrylate (col.17, l.30-42). One of ordinary skill in the art would have recognized that Yang et al and Goldberg et al are analogous insofar as both references are concerned with forming biocompatible lubricious hydrophilic coatings on medical devices for insertion into human bodies or surgical instruments such as lens glides.

Therefore, it would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made that methoxy polyethylene glycol monomethacrylate of Goldberg et al is a well known polyethylene glycol lubricious

coating in the art of medical devices and is the typical form of the generic polyethylene glycol lubricious hydrophilic coatings used in the art. Thus, it would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made to use the methoxy polyethylene glycol monomethacrylate of Goldberg et al as the polyethylene glycol coating of Yang et al because methoxy polyethylene glycol monomethacrylates are known in the art to be preferred as a hydrophilic polyethylene glycol coating, as taught by Goldberg et al and since it is obvious to one having ordinary skill in the art to select a known material on the basis of its suitability depending on the intended end results of the article.

Regarding claims 32-42, the monomethacrylate is the reactive substituent component comprising an ethylenically unsaturated group such as methacrylic groups. The polyethylene glycol is the lubricity enhancing component as an alkylene oxide. Specifically, Goldberg et al provides an example of using a high molecular weight mPEGMA (col.17, l.40-42). The second substituent component effective to reduce hydrolysis of said lubricity enhancing component is methoxy, which is an alcoxy group having 1 carbon atom, which is a specific hydrocarbyl group.

Regarding claims 43, 46, and 51-56, Yang et al and Goldberg et al teach all that is claimed in claim 42 as shown above, and teach that the lubricity enhancing component is polyethylene glycol. Yang et al and Goldberg et al fail to teach that mPEGMA comprises mPEGMA of at least three different molecular weights. However, Goldberg et al teach mPEGMA of various PEG molecular weights are used (col.17, l.39-42) and teach that more than one hydrophilic monomer is used together (col.11, l.10-14) and teach that optimum results of the coating are obtained by selection of a combination of process parameters, monomers, and conditions (col.10, l.50-54). One of ordinary skill in the art would have recognized that through routine experimentation one would arrive at the optimum combination of monomers including three different molecular weight mPEGMA such as 1100, 526, and 360, depending on the intended end result of the coating and article the coating is applied, as taught by Goldberg et al.

Therefore, it would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made to select the mPEGMA as a combination of at least three different molecular weight mPEGMA wherein at least one of said three is has a molecular weight of 1100, or 526, or 360, absent the showing of unexpected result, since Goldberg et al teach that it is known to combine multiple hydrophilic components to

form the coating and that mPEGMA is selected form various molecular weight mPEGMA and since the specific selection of monomers in the coating are determined through routine experimentation to optimize the results of the coating on the end product.

ANSWERS TO APPLICANT'S ARGUMENTS

12. Applicant's arguments regarding the claim objections and the 35 U.S.C. 112 and 103 rejections of record in the previous Office Action mailed November 7, 2005 have been considered but they are moot since the rejections have been withdrawn.

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Valint, Jr. et al (USPN 5,525,691).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher P. Bruenjes whose telephone number is 571-272-1489. The examiner can normally be reached on Monday thru Friday from 8:00am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Harold Pyon can be

reached on 571-272-1498. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher P Bruenjes
Examiner
Art Unit 1772

CPB CPB
March 30, 2006

/David Pyon/
HAROLD PYON
SUPERVISORY PATENT EXAMINER
1772

3/31/06